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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/968,368	11/13/97	NOLAN	A-6426[illegible]

HM22/0201
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EXAMINER
VANDER VEGT,F

ART UNIT	PAPER NUMBER
1644	7

DATE MAILED: 02/01/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/963,368	Applicant(s) Nolan, GP
	Examiner F. Pierre VanderVegt	Group Art Unit 1644

X Responsive to communication(s) filed on *Dec 11, 1998*.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

X Claim(s) *16-28* ~~is~~/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

X Claim(s) *16-28* ~~is~~/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

X Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- *SEE OFFICE ACTION ON THE FOLLOWING PAGES* ---

DETAILED ACTION

This application is a divisional of application S.N. 08/789,333, which is a divisional of application S.N. 08/589,108, which is a divisional of application S.N. 08/589,911.

Claims 1-15 were previously canceled. New claims 23-28 have been added.

Claims 16-28 are currently pending in this application.

1. In view of the amendment and the declaration under rule 1.131 by Garry P. Nolan filed December 11, 1998, no previous grounds of rejection are maintained. It should be here noted that this action is made **NON-FINAL**.

Claim Rejections - 35 U.S.C. § 112

2. Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim is drawn to a fusion partner which comprises a "multimerization sequence" which is not disclosed in the specification or claims as originally filed. Applicant contends that support for the recitation is found at page 6, line 1 to page 18, line 29 of the specification, but support can only be found for "dimerization" at page 15, line 5 to line 23, for example. The term multimerization encompasses as many copies of a peptide which can be physically or stearically joined to a fusion partner as part of a construct as opposed to dimerization, which encompasses only two copies of the peptide as part of the construct. Applicant's original specification does not teach or contemplate fusion partners which can confer the ability to join more that two copies. The recitation of "multimerization sequence" in claim 27, therefore, constitutes new matter which must be removed in response to this Office Action.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 16-22 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,639,595 to Mirabelli et al (A on form PTO-1449, of record) in view of Kaufman (U on form PTO-892).

The '595 patent teaches a library of plasmid vectors which contains random oligonucleotides contained a population of 2.7×10^8 sequences (column 15, lines 11-24 in particular), which comprises at least 10^8 different nucleic acids. The '595 patent further teaches transfected mammalian cells with the library incorporated into the genome as evidenced by surface expression of proteins encoded by the library sequences (column 15, lines 40-55 in particular). The '595 patent does not teach retroviral vectors. However, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to substitute retroviral vectors, which were well known at the time the invention was made, for the plasmid vectors of the '595 patent based upon the teachings of Kaufman. Kaufman teaches that methods of DNA transfer, which includes plasmids, usually transform 5-50% of the target cells and express the DNA transiently, ultimately losing the transferred DNA from the population (page 495 in particular). Kaufman teaches that retroviral vectors, on the other hand, have significant advantages, in that they can transduce genes into a variety of cell types and into a variety of species and can introduce nearly 100% of the host cells. One would have been motivated to substitute retroviral vectors for the plasmid vectors taught by the '595 patent based on the teaching of Kaufman that retroviral vectors allow the practitioner "to produce stable cell lines as a result of retrovirus integration into the host chromosome" (paragraph bridging pages 494 and 495 in particular).

4. Claims 16-26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,639,595 to Mirabelli et al (A on form PTO-1449, of record) in view of Kaufman (U on form PTO-892) and Nilsson et al(V).

The '595 patent and Kaufman have been discussed supra. The combined references do not teach the expression of fusion proteins [claims 23-26]. Nilsson et al teaches that fusion proteins are constructed for a variety of purposes, such as increasing the stability of the product [claim 26], both during purification or in vivo use of the product (pages 570-571 in particular). Nilsson et al further teaches that fusion of a desired protein product with a 'handle' that has unique binding characteristics facilitates purification (rescue) of the desired protein so that the protein which confers a particular phenotype of interest on the host cell can be retrieved for further study [claim 25]. Nilsson et al also teaches that a further reason to construct a fusion protein would be for targeting of protein drugs (page 572 in particular)[claim 24]. It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to combine the teachings of Nilsson et al with those of the '595 patent and Kaufman. One would have been motivated to combine these teachings with a reasonable expectation of success based on the teachings of Nilsson et al that fusion proteins can be constructed for a variety of reasons ranging from protein recovery to therapeutic uses.

Conclusion

5. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and even-numbered Mondays (on 1999 365-day calender) from 7:00 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

January 28, 1999
F. Pierre VanderVegt, Ph.D.
Patent Examiner
Art Unit 1644

David A. Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644